EXHIBIT 4

K080763

510(k) Summary

MAY 30 2008

Submitted by:	Talley Medical/Jaxports 4740 Jadestone Dr. Williamston, MI 48895
Contact Person:	Jack Van Dyke Talley Medical 1070 E. Wieland Rd. Lansing, MI 48906 517-290-0089
Device Information	TableGard Pressure Relieving Patient Warming Mattress Model TG700ht Product Code DWJ 21CFR 870.5900 Class II Product Code FNM 21CFR 880.5550 Class II 510k Exempt
Common name	Patient Warming system Thermal Regulating System Alternating air mattress
Predicate Devices	E. KO 11859 Klinamed Thermal Mat & Controller F. KO 01149 Bair Hugger Patient Warming System G. KO 062794 PRN ThermalCare Patient Warming System H. KO 501419 Inditherm Patient Warming System
Description of the Device:	The TableGard Pressure Relieving Patient Warming Mattress system consists of an alternating air mattress (patient support surface) with air pump, and a connectable and thermally regulated warm air blower unit. The air mattress is enclosed in a vinyl and polyurethane cover, which is in turn fitted with air inlet and outlet ports to receive and recirculate warmed air within the air mattress cover under the patient. The patient is warmed by conduction of heat (regulated between 34° and 40° C) thru the polyurethane cover. The air pump and air blower unit operate on 110V, but there is no electrical contact between the control devices and the patient support mattress. The air pump alternately cycles pressures between sections of the mattress to relieve interface pressure against the patient's soft tissues.

Intended Use: The TableGard Pressure Relieving Patient Warming Mattress is intended to prevent or treat hypothermia and to provide warmth and pressure relief to patients during extended periods of immobilization. The TableGard should be used in circumstances in which patients could become cold and/or require long periods of static posture.

The TableGard Pressure Relieving Patient Warming Mattress is intended for use on operating tables, surgical and diagnostic surfaces in hospitals or surgical centers to prevent and treat hypothermia and to reduce the occurrence of pressure ulcers.

Patient Population: Adult and pediatric

Comparison to Predicate Devices: See comparison Table 1 in Section 12.

The differences between the TableGard Pressure Relieving Patient Warming Mattress and the predicate devices are minimal. The predicate devices are all external, thermal regulation systems that consist of a device that is placed in contact with the patient, and connected to a control unit that provides physician determined temperature controls.

Functional and Safety Testing:

The TableGard system was evaluated in terms of achieved surface temperatures under normal operating conditions and in conditions of possible single fault failures to determine if an acceptable risk of thermal injury existed. Functional temperature testing shows that the warming System does not result in simulated skin temperatures that would cause thermal injury.

The TableGard system was also evaluated in terms of Interface pressure relief between the patient and the support surface.
Functional testing shows that the interface pressure was measured as fully relieved on a cyclical and consistent basis.

Conclusion: Based upon the testing and comparison, we believe the TableGard Pressure Relieving Patient Warming Mattress to be substantially equivalent to predicated devices and that there is no new safety or effectiveness issue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2008

Talley Medical
c/o Mr. Jack Van Dyke
1070 E. Wieland Road
Lansing, MI 48906

Re: K080763
Talley Tablegard Pressure Relieving Patient Warming Mattress
Regulation Number: 21 CFR 870.5900
Regulation Name: System, Thermal Regulating
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: May 15, 2008
Received: May 18, 2008

Dear Mr. Dyke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(K) No. K080763

Device name: TALLEY TABLEGARD PRESSURE RELIEVING PATIENT WARMING MATTRESS

Indications for Use:

Use of the Talley TableGard Pressure Relieving Patient Warming Mattress is indicated for use for patients that may be benefited by the application of heat during surgical procedures to help maintain normothermia. It is intended for use in the operating rooms, recovery rooms, intensive care departments, emergency rooms in hospitals and outpatient clinics to assist patients to maintain normal body temperature. The TableGard mattress also includes alternating air support to relieve pressure against soft tissues during prolonged periods of immobilization.

Prescription Use____X____ OR Over the Counter Use_____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrance of CDRH, Office of Device Evaluation (ODE)

Donna R. Kuhnel

(Division Sign-Off)
Division of Cardiovascular Devices

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